

## REMARKS

The applicants have studied the Office Action dated March 26, 2003, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 20-24, 35, 38, and 58 have been cancelled without prejudice or disclaimer, and claims 1, 34, and 36 have been amended; thus, claims 1-5, 7-19, 34, 36, 39-40, and 59-60 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

The applicants acknowledge the election of Group I, Species D shown in Figs. 19-20b, as defined by claims 1-5, 7-24, 34-36, 38-40, and 58-60. However, the applicants continue to request inclusion of the species shown in Figs. 21(a)-22(b), 24(a)-24(b), 27(a)-27(b), and 29(a)-29(b) in the election, as these species are not patentably distinct from the species shown in Figs. 19-20(b). Further, the applicants submit that elected claims 1 and 34 are generic to the embodiments shown in Figs. 19-22(b), 24(a)-24(b), 27(a)-27(b), and 29(a)-29(b). In the illustrated embodiments, the piston includes a first piston member and a second insert member. The insert also includes one or more holes or passages through the insert (hole 2002 through insert 2000 in Figs. 20(a)-20(b), holes 2102 and 2104 through insert 2100 in Figs. 21(a)-21(b), holes 2202, 2204, and 2206 through insert 2200 in Figs. 22(a)-22(b), hole 2408 through insert 2400 in Figs. 24(a)-24(b), hole 2704 through insert 2700 in Figs. 27(a)-27(b), and holes 2902 through insert 2900 in Figs. 29(a)-29(b)) from the first side to the second side of the insert to permit admittance of a sterilization agent to the first side of the insert, as defined by claims 1 and 34. If the requested inclusion is not allowed by the Examiner, the applicants recognize that, upon the allowance of a generic claim, the applicants will be entitled to consideration of claims to additional species, which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141.

Claims 1-5, 7-24, and 34-36 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-19, 21-24, and 34-36 of copending Application No. 09/698,783. With respect to claims 20-24 and 35,

these claims have been cancelled without prejudice or disclaimer; thus, this rejection is now moot. With respect to independent claim 1 and claims 2-5 and 7-19 depending therefrom, these claims have been amended to include the language recited in former claim 38. Similarly, with respect to independent claim 34 and claim 36 depending therefrom, these claims have been amended to include the language recited in former claim 58. Former claims 38 and 58 were not provisionally rejected under the doctrine of obviousness-type double patenting. Thus, it is respectfully submitted that the provisional rejection of claims 1-5, 7-24, and 34-36 under the judicially created doctrine of obviousness-type double patenting should now be withdrawn.

The Examiner required that Figures 1-3b be amended to include a legend such as "Prior Art". The applicants have amended the drawings as indicated in red on the attached copies of Figures 1-3b. Therefore, it is respectfully requested that the objection to the drawings be withdrawn, and the requirement for new formal drawings be held in abeyance until receipt of a Notice of Allowance.

Claim 4 and 17 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Claims 4 and 17 recite that the second member is made of stainless steel. The Examiner indicated that the specification disclosed the second member being made of metal, but not specifically stainless steel. However, the applicants respectfully point out that page 21, lines 1-5 of the specification discloses that the second member (i.e., insert) may be made of "hard plastic, stainless steel or other preferably relatively stiff material." Therefore, withdrawal of the rejection of claims 4 and 17 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 21-24 and 36 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. With respect to claims 21-24, these claims have been cancelled without prejudice or disclaimer; accordingly, this rejection is now moot. With respect to claim 36, the Examiner indicated that claim 36 depended from itself. In response, the applicants have amended claim 36

to depend from 34. Thus, withdrawal of the rejection of claim 36 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 1-5, 7-18, 20, 34-36, 38, 40, 58, and 60 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kakimi et al. Claims 39 and 59 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kakimi et al. With respect to claims 20 and 35, these claims have been cancelled without prejudice or disclaimer; thus, these rejections are now moot. With respect to claims 1-5, 7-18, 34, 36, 39, 40, 59, and 60, these rejections are respectfully traversed.

Embodiments of the present invention are directed to an apparatus for dispensing a medication fluid, which includes a reservoir and a piston. The reservoir is adapted to contain the fluid and is adapted for use with a drive system having a linear actuation member. Referring to Fig. 19, the piston includes a first piston member 1900 having an external proximate side and an external distal side. The first member 1900 is adapted to be slidably mounted within a reservoir and to form at least part of a fluid-tight barrier within the reservoir. The external proximate side of the first member 1900 is adapted to contact the fluid and is made of a material having a first stiffness, and the external distal side of the first member 1900 forms an opening leading to a cavity and is adapted to releasably engage the linear actuation member. The piston also includes a second insert member 1902 having a first side and a second side. The first side of the second member 1902 is disposed within the cavity of the first member 1900. Additionally, the first side of the second member 1902 is adjacent to the external proximate side of the first member 1900, and is made of a material having a stiffness that is greater than the first stiffness. As a result, the second member 1902 provides stiffness to the first member 1900, and reduces undesirable deformation of the piston. Further, referring to Figs. 20(a)-20(b), the second insert member 2000 may include one or more passages 2002 through the second member 2000 from the first side to the second side of the second member 2000 to permit admittance of a sterilization agent to the first side of the second member 2000.

Amended claim 1, and claims 2-5 and 7-19 depending therefrom, recite “the external distal side [of the first member] is adapted to releasably engage the linear actuation member” and

“the second member further including one or more passages through the second member...to permit admittance of a sterilization agent to the first side of the second member.” Amended claim 34, and claim 36 depending therefrom, recite similar language. The Kakimi et al. reference fails to disclose, teach, or suggest a piston including a first member that is adapted to be releasably coupled to a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.

The Kakimi et al. reference is directed to a medical syringe. Referring to Figs. 1 and 2, the syringe 2 includes a syringe body 3 and a plunger 4 fitted in the syringe body 3. The plunger 4 comprises an elastic cover 9 (first member) and a plunger body 5 (second member), and the elastic cover 9 is fitted over the plunger body 5 from the front. The plunger body 5 includes three components 6, 7, and 8 that are fitted to one another in an axial arrangement. As shown in Fig. 2, when the plunger body 5 is fitted together, the plunger body 5 has its first side at the tip of the third component 8, and its second side at the backplate 62 of the first component 6. Although the third component 8 includes air vents 85, these vents 85 are blocked by the first and second components 6 and 7 of the plunger body 5. Thus, these vents would not permit admittance of a sterilization agent from the second side to the first side of the plunger body 5, as recited in the claims. Further, the elastic cover 9 (first member) is not adapted to releasably engage a linear actuation member. Instead, the plunger body 5 (second member) is coupled to the linear actuation member. Therefore, the Kakimi et al. reference does not disclose, teach, or suggest a piston including a first member that is adapted to releasably engage a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.

Accordingly, withdrawal of the rejections of claims 1-5, 7-18, 20, 34-36, 38, 39, 40, 58, 59, and 60 under 35 U.S.C. §§ 102(e) and 103(a) is respectfully requested.

Claims 1, 2, 4-9, 20, and 34-36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Butcher et al. With respect to claims 20 and 35, these claims have been cancelled

without prejudice or disclaimer; thus, this rejection is now moot. With respect to claims 1, 2, 4-9, 34, and 36, this rejection is respectfully traversed.

Amended claim 1, and claims 2 and 4-9 depending therefrom, recite “the external distal side [of the first member] is adapted to releasably engage the linear actuation member” and “the second member further including one or more passages through the second member...to permit admittance of a sterilization agent to the first side of the second member.” Amended claim 34, and claim 36 depending therefrom, recite similar language. The Butcher et al. reference fails to disclose, teach, or suggest a piston including a first member that is adapted to releasably engage a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.

The Butcher et al. reference is directed to a composite piston for a hypodermic syringe. Referring to Figs. 1 and 9, the piston 2 includes an elastic outer sheath 10 (first member) and a rigid inner sheath 4 (second member). However, the outer sheath 10 (first member) is not adapted to releasably engage a linear actuation member. Instead, the inner sheath 5 (second member) is coupled to the linear actuation member. Further, the inner sheath 4 (second member) does not include any passages to permit admittance of a sterilization agent to the first side of the inner sheath 4. Thus, the Butcher et al. reference does not disclose, teach, or suggest a piston including a first member that is adapted to releasably engage a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.

Accordingly, withdrawal of the rejection of claims 1, 2, 4-9, 20, and 34-36 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 1-5, 7-10, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Namey, Jr. With respect to claim 20, this claim has been cancelled without prejudice or

disclaimer; thus, this rejection is now moot. With respect to claims 1-5 and 7-10, this rejection is respectfully traversed.

Amended claim 1, and claims 2-5 and 7-10 depending therefrom, recite “the external distal side [of the first member] being adapted to releasably engage the linear actuation member” and “the second member further including one or more passages through the second member...to permit admittance of a sterilization agent to the first side of the second member.” The Namey, Jr. reference fails to disclose, teach, or suggest a piston including a first member that is adapted to releasably engage a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.

The Namey, Jr. reference discloses a plunger used in a syringe. Referring to Figs. 2 and 3, the plunger 20 includes a rubber exterior 32 (first member) overmolded onto a hard plastic core 30 (second member). However, the rubber exterior 32 (first member) is not adapted to releasably engage a linear actuation member. Instead, the plastic core 30 (second member) includes a button 26 for coupling to a linear actuation member (col. 3, lines 2-7). Further, the plastic core 30 (second member) does not include any passages to permit admittance of a sterilization agent to the first side of the plastic core 30. Thus, the Namey, Jr. reference does not disclose, teach, or suggest a piston including a first member that is adapted to releasably engage a linear actuation member and a second member that includes one or more passages through the second member to permit admittance of a sterilization agent to the first side of the second member, as recited in the claims.


Accordingly, withdrawal of the rejection of claims 1-5, 7-10, and 20 under 35 U.S.C. § 102(b) is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all of the elected claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney at (818) 576-5291.

Respectfully submitted,

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